DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
National Institute for Occupational
Safety and Health (NIOSH)
National Personal Protective
Technology Laboratory (NPPTL)
P.O. Box 18070
Pittsburgh, PA 15236-0070
Phone: 412-386-4000
Fax: 412-386-4051

May 19, 2006

LETTER TO ALL RESPIRATOR MANUFACTURER'S

Subject: **Summary of 4/27/06 Manufacturers' Meeting**

During the public meeting held by the National Personal Protective Technology Laboratory (NPPTL) Technology Evaluation Branch on April 27, 2006 at the Key Bridge Marriott in Arlington, Virginia, the following topics were presented and discussed:

NPPTL Isoamyl Acetate (IAA) Fit Testing Policies and Procedures

An overview of current IAA fit test procedures and policies was presented along with a summary of a study that was performed to validate the effectiveness of the IAA fit test that NPPTL utilizes. For this study, several approved half-mask and full facepiece respirators were purchased from the open market. Both the IAA fit test required by Title 42, *Code of Federal Regulations*, Part 84 (42 CFR 84) and PortaCount ™ test (utilizing NPPTL exercises) were performed according to the procedures and policies as specified by 42 CFR 84 and the May 18, 2005 Letter to All Respirator Manufacturers regarding Air-Purifying Fit Test Subject Selection. The findings of this study are as follows:

- Respirators with overall passing fit factors on the PortaCount ™ for the type of respirator evaluated did not always get passing PortaCount ™ fit factors when performing the individual IAA test excercises…i.e. one or two exercises resulted in a fit factor less than that which would be required by users in the workplace.

- Respirators that had very good fit factors on the PortaCount ™ did not always pass IAA Testing. This has been attributed to the fact that some individuals are more sensitive to IAA and detect it at much lower levels than 1 PPM which is the current concentration utilized for screening test subjects.

- Cartridge, canister and/or filter weight plays an essential role in respirator fit.

Based upon these findings, NPPTL announced that it is implementing the following policies effective immediately:

- Surrogate cartridges or canisters used for fit testing of air-purifying respirators must be of an equivalent weight and breathing resistance as the actual filter or cartridge for which approval is being sought.

- Test subjects will be screened during each visit for their capability to detect IAA prior to conducting an IAA fit test.

- Test subjects will be required to don the mask and obtain a positive and/or negative seal check per the manufacturer's User's Instructions three times. Upon obtaining a seal check after donning the mask for the third time, the subject will wear the mask for five minutes to become acclimated to the respirator prior to entering the chamber for the fit test.

- Test subjects who detect IAA odor prior to initiation of the exercises by the test administrator will exit the chamber, perform a seal check, and doff the respirator. The subject will then be escorted to an area free of IAA and will re-don the respirator. Once a good seal is obtained and confirmed by performing a positive and/or negative seal check, the subject will once again enter the chamber. If the odor is again detected before the test administrator formally initiates the test, it is assumed that the respirator can not maintain a good seal and that trial will be counted as a test failure.

- For extensions of approval where cartridges, canisters, filters, and/or accessories are added that yield heavier configurations than those previously fit tested, NIOSH will perform a new IAA fit test to determine the ability of the facepiece to obtain and maintain a fit with the heavier cartridges, canisters, filters, and/or accessories.

As an effort to insure that respirators are properly fitted on end users, NPPTL is requiring that all air-purifying approval requests submitted after July 1, 2006 address the fact that weight affects respirator fit. Manufacturers are required to add statements to the User's Instructions that indicate that the fit test should be performed with the exact configuration that is to be worn by the end user in the workplace including all accessories and personal protective equipment that may interfere with the fit of the respirator. Where the configuration that is to be worn by the end user is not appropriate for fit testing, a specific respirator facepiece with cartridges, canisters and/or filters representative in weight and configuration along with all accessories and personal protective equipment that may interfere with the fit of the respirator may be used for fit testing. An additional caution, stated as follows, will be required on all labels:

> **Caution FF**: Respirators are to be fit tested prior to use with the heaviest cartridges, canisters, filters and/or accessories intended to be used. Fit testing should also be conducted while wearing all personal protective equipment intended to be used. See User's Instructions for fit test requirements.

NPPTL also recognizes that the following issues need to be addressed. Information regarding each of these issues will be shared as these issues are addressed:

- The relevance of continuing to require overlap sizes for IAA fit testing respirators that are available in multiple sizes.

- Developing alternative IAA pre-screening procedures for determining test subject suitability.

- Developing procedures to insure that exercises used for the IAA fit test by NPPTL are more consistent and reproducible between test subjects.

NPPTL Equipment Malfunctions

In the past, NPPTL has experienced infrequent equipment malfunctions such as power outages, refrigerant leaks and sensor failures that are beyond its control. If test or conditioning equipment malfunctions, NPPTL's policy is to terminate testing or conditioning at that point in time in which the problem is identified. All testing or conditioning affected will be repeated at no expense to the applicant; however, the applicant should insure that it has enough additional hardware available to repeat testing or conditioning in the event of such a malfunction.

Product Audit Decision Logic Concept

Respirator product audits are obtained by purchasing units from the open market. In certain situations, product audit samples are also obtained during manufacturing on-site compliance audits. These samples are performance-tested and verified for conformance to the applicable standards addressed in 42 CFR 84. A Respirator Audit Logic Concept is being proposed for implementation by the NPPTL Technology Evaluation Branch for selecting NIOSH-approved respirators for product audits utilizing an audit logic algorithm. The Respirator Audit Logic for Respirator Product Audits is designed to prioritize respirators based on past performance and other characteristics.

NPPTL Processing Times and Priorities

An analysis of the time distribution for approval activities for March 2006 was presented. For all applications completed in March 2006, the total time was 62.25 average days compared to 103 average days in March of 2005. The time distribution between major activities was:

22.5 days – Initial Review
7.5 days – Testing
21 days – QA Review
11 days – Final Review

Note that the QA activity begins concurrently with testing and the time noted for QA is only that for which QA time exceeded testing time. In other words, the total time in QA was 21 days plus 7.5 days.

This represents a significant improvement over 2005 and an average processing time below the 90 day target. However this average contains both simple and complex projects. We note that there are areas needing attention. In initial review, over 25% of the projects required over 30 days. In QA review, 20% of the projects required over 30 days. In final review, 10% of the projects required over 90 days.

NPPTL is considering several possible methods of expediting the process in addition to that already stated in the Standard Application Procedures. NPPTL recognizes a need to improve and simplify the Standard Application Form. NIOSH is also considering modifying the Initial

Review process by assigning testing after only assuring that the required information is submitted then continuing with more complete analysis concurrent with the QA review phase.

QA frequently waits for corrections of the matrix, the QA manual and related documents. NPPTL is considering notifying the manufacturer when the project has passed testing and scheduling a conference to address QA where the parties will set a limited time for correction or rejection. NPPTL is also considering making its matrix verification software available to manufacturers and simplifying the matrix requirements. The latter will require some collaborative efforts with the manufacturers.

Update on the Total Inward Leakage (TIL) Half-Mask Project

Benchmark testing for 101 half-mask respirator models has been completed and the data analysis has been started. Data shows a wide range of fit factors for the data that has been collected. A public meeting to present the findings of this study will be scheduled for later this year.

Update on the QA Module

The QA module has been revised and the preamble and regulatory language has been drafted. The QA module no longer includes administrative aspects such as new fee structures. The module now focuses strictly on QA. More emphasis is being placed on consumer risk rather than manufacturer risk. The impact analysis is being completed in order to start the internal review process. The intent is to publish the proposed rule later this year.

Update on Concurrent Approval Process for the NFPA 1981 CBRN Standard

NPPTL is working in cooperation with NFPA to develop a concurrent approval process that is acceptable to those involved.

Issues Not discussed: CBRN PAPR standard

The next meetings are **tentatively** scheduled as follows:

All Manufacturer's meeting - October 2, 2006
CBRN PAPR meeting - October 3 and 4, 2006.
Note that NPPTL is awaiting approval from higher organizational levels to proceed with this program.
NPPTL research overview - October 3 and 4, 2006
Location: Holiday Inn Express, South Hills, Pittsburgh, PA

The slides that were presented at the meeting will be available for download from the NPPTL web site. If you have any further questions please feel free to contact NPPTL at 412-386-4000.

Sincerely yours,

William A. Hoffman
Acting Chief
Technology Evaluation Branch
National Personal Protective Technology Laboratory